RESEARCH PAPER

# Ayurvedic Intervention In Ibs: A Clinical Trial On A Herbal Formulation's Effectiveness

**Rohini Jat[1], Preeti Gavali[2], Reetu Sharma[3], Kishor Gavali[4], Manita Ahlawat[5], Santoki Akash Mansukhbhai[6], Harshad Jain[7], Jahan Peston Jamas[8]**

[1] Assistant Professor, SBSJSAMC & Hospital, Bewar Road, Farrukhabad (U.P) rohinichoudhary1996@gmail.com https://orcid.org/0000-0002-3206-3247
[2] Senior Assistant Professor, Department of Roga Nidana Evam Vikriti Vigyana, National Institute of Ayurveda, Jaipur, Rajasthan, India. preeti.620@gmail.com, https://orcid.org/0000-0002-5784-5341
[3] Associate Professor, Department of Roga Nidana Evam Vikriti Vigyana, National Institute of Ayurveda, Jaipur, Rajasthan, India. drreetusharma@gmail.com, https://orcid.org/0000-0001-9090-4887
[4] Research officer, M.S. Regional Ayurveda Research Institute (CCRAS), Banipark, Jaipur dr.kishorgavali@gmail.com
[5] Senior Assistant Professor, Department of Roga Nidana Evam Vikriti Vigyana, National Institute of Ayurveda, Jaipur, Rajasthan, India. dr.ahlawatmanita16@gmail.com https://orcid.org/0000-0003-2588-5135
dr.ahlawatmanita16@gmail.com https://orcid.org/0000-0003-2588-5135
[6] PG Scholar, Department of Roga Nidana Evam Vikriti Vigyana, National Institute of Ayurveda, Jaipur, Rajasthan, India, akashsantoki17101997@gmail.com, https://orcid.org/0009-0000-3698-3908
[7] Ayurveda Medical Practitioner, Bombay Hemp Company, Mumbai, Maharashtra, India. DrHarshad.J@boheco.com
[8] Chief Strategy Officer, Bombay Hemp Company, Mumbai, Maharashtra, India. jahan.p@boheco.com

***Corresponding Author:** Dr. Preeti Gavali
*Senior Assistant Professor Department of Roga Nidana Evam Vikriti Vigyana National Institute of Ayurveda, Jaipur, Rajasthan, India Email: preeti.620@gmail.com

**Abstract:**
**Background:** Irritable Bowel Syndrome (IBS) is a chronic functional gastrointestinal disorder affecting quality of life. It presents with abdominal discomfort, bloating, altered bowel habits, and digestive disturbances. Conventional treatments offer symptomatic relief but often lack long-term efficacy. Ayurveda identifies IBS with Grahaṇī and Pakvāśaya disorders, primarily caused by Vāta Doṣa vitiation. Herbal formulations with digestive and gut-regulating properties may offer a holistic therapeutic approach. This study evaluates the efficacy and safety of Digestive Health Capsules—an Ayurvedic formulation containing Bilva (Aegle marmelos), Kuṭaja (Holarrhena antidysenterica), Śuṇṭhī (Zingiber officinale), and Vijayā (Cannabis sativa)—in IBS management. **Methods:** A single-arm, open-label clinical trial was conducted at the National Institute of Ayurveda (NIA), Jaipur. A total of 40 IBS patients were enrolled based on specific inclusion and exclusion criteria. Participants received Digestive Health Capsules twice daily for eight weeks. The primary outcome was assessed using the IBS-Quality of Life (IBS-QOL-36) scale, and statistical analysis was performed using paired t-tests and Wilcoxon signed-rank tests. **Results:** The study demonstrated a significant improvement ($P<0.0001$) in multiple IBS-QOL parameters, including reduced abdominal discomfort, bloating, urgency, anxiety, dietary restrictions, and impact on daily activities. The formulation was well-tolerated, with no reported adverse effects. **Conclusion:** The Ayurvedic herbal formulation showed promising results in alleviating IBS symptoms and improving patients' quality of life. Its holistic action on digestion, gut motility, and stress management highlights its potential as an effective natural alternative for IBS treatment. Further controlled studies are recommended to validate these findings.

**Keywords:** Irritable Bowel Syndrome, Ayurveda, Grahaṇī, Cannabis sativa, Holarrhena antidysenterica, Aegle marmelos, Zingiber officinale, Gut-Brain Axis, IBS-QOL-36

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## Introduction

Irritable Bowel Syndrome (IBS) is a prevalent functional gastrointestinal disorder that significantly affects individuals' quality of life.[1] It is characterized by chronic abdominal discomfort, bloating, altered bowel habits, and digestive disturbances without any detectable structural abnormalities.[2] The condition is often referred to by various names, including spastic colon, mucous colitis, and nervous diarrhea, highlighting its diverse symptomatology. IBS is a chronic and relapsing disorder that does not cause severe complications but can considerably impact daily activities, productivity, and emotional well-being.[3]

Despite extensive research, the exact cause of IBS remains elusive. However, a combination of factors, including altered gut motility, visceral hypersensitivity, gut-brain axis dysfunction, and psychosocial stressors, is believed to play a crucial role in its pathogenesis.[4] The gut microbiota, immune activation, and dietary influences also contribute to symptom development and

*Author for Correspondence: mr.rhl2612@gmail.com

exacerbation. IBS is classified into subtypes based on predominant bowel movement patterns—IBS-D (diarrhea-predominant), IBS-C (constipation-predominant), IBS-A (alternating between diarrhea and constipation), and IBS-U (unclassified). These subtypes vary in their clinical presentation, requiring a personalized treatment approach.[5]

Multiple triggers contribute to the onset and severity of IBS symptoms. Infections, such as post-infectious gastroenteritis, have been linked to IBS development, while psychological stress and lifestyle changes are known to exacerbate symptoms.[6] Dietary habits, including food intolerances, excessive consumption of processed foods, and inadequate fiber intake, further influence disease progression. Although IBS is not life-threatening, its chronic nature often leads to persistent discomfort, fatigue, anxiety, and depression, significantly affecting an individual's well-being.[7]

In India, the prevalence of IBS is estimated to be around 15-20% of the population, with a higher incidence among young adults and women.[8] Socioeconomic factors, dietary patterns, and stress-related issues contribute to its widespread occurrence. Due to its relapsing nature, IBS often leads to increased healthcare utilization, work absenteeism, and reduced productivity, making it a significant public health concern.[9]

From an Ayurvedic perspective, IBS shares similarities with Grahaṇī and Pakvāśaya disorders, primarily caused by the vitiation of Vāta Doṣa, often accompanied by Pitta or Kapha imbalances. Ayurveda emphasizes the gut-brain connection, recognizing that mental disturbances such as stress, anxiety, and emotional turmoil aggravate Vāta, thereby disrupting digestive function.[10] Classical Ayurvedic texts describe conditions resembling IBS, including Vātaja Atisāra (diarrheal disorders), Sangraha Grahaṇī (malabsorption syndromes), and Pravāhikā (dysenteric conditions), all of which exhibit overlapping symptoms with IBS.

Herbal formulations have been widely used in Ayurveda for gastrointestinal disorders, addressing both the physiological and psychological components of IBS. This study explores the potential benefits of Digestive Health Capsules, an Ayurvedic formulation containing Bilva (Aegle marmelos), Kuṭaja (Holarrhena antidysenterica), Śuṇṭhī (Zingiber officinale), and Vijayā (Cannabis sativa). These herbs are traditionally known for their digestive, antispasmodic, and gut-regulating properties.

This research aims to analyze IBS from an Ayurvedic lens, draw parallels with classical descriptions, and evaluate the effectiveness of Digestive Health Capsules in managing IBS symptoms. By assessing its impact on symptom severity and quality of life, this study seeks to provide a holistic and natural approach to IBS management, integrating traditional wisdom with modern clinical research.

## 2. Methodology

**Study design:** This research is an open-label, single-arm, single-center clinical trial aimed at assessing the safety and efficacy of Digestive Health Capsules in managing Irritable Bowel Syndrome (IBS). The study was conducted at the National Institute of Ayurveda (NIA), Jaipur, and was duly registered with the Clinical Trials Registry of India (CTRI/2022/03/041004). Prior to initiation, ethical clearance was obtained from the Institutional Ethical Committee of NIA, Jaipur (No. IEC/ACA/2021/02-83) to ensure compliance with ethical and regulatory standards.

**Subject Selection** A total of 40 patients diagnosed with IBS (both men and women) were enrolled in the study based on the inclusion and exclusion criteria. Written informed consent was obtained from all participants before enrollment.

**Inclusion criteria-** The study included male and female participants between the ages of 18 to 65 years who were diagnosed with Irritable Bowel Syndrome (IBS) based on the IBS diagnostic scale. Individuals who were non-regular users of cannabis (less than three times per week) and willing to abstain from cannabis use for at least one week prior to and throughout the study were considered for enrollment. Additionally, participants needed to have normal liver function (AST: 10-40 U/L, ALT: 7-56 U/L) and normal renal function (serum creatinine $< 133$ µmol/L, eGFR $\geq 60$).[11] To maintain consistency in the study, subjects had to agree to avoid other products with similar benefits for the duration of the trial. Furthermore, participants were expected to refrain from alcohol, caffeine, and nicotine consumption during the study period.

**Exclusion Criteria**- Participants were excluded from the study if they had a known hypersensitivity or history of adverse events related to cannabis or cannabinoids. Individuals currently using opioids or other anxiety medications were also not eligible. Patients with significant cardiac conditions, including uncontrolled hypertension, arrhythmia, or a history of myocardial infarction, were excluded due to potential health risks. Additionally, individuals with a current substance use disorder or a lifetime history of cannabis dependence were not considered for participation. Pregnant and lactating women, as well as those planning pregnancy, were excluded to prevent any potential risks to maternal and fetal health. Regular users of cannabis (three or more times per week) or those taking cannabinoid-based medications within seven days prior to study entry were also ineligible. Positive urine screening for substance abuse, including alcohol, cocaine, amphetamines, and opioids, led to exclusion from the trial. Furthermore, individuals with systemic or cutaneous diseases that could interfere with study procedures were not included. Lastly, participants who had been part of another clinical trial for the same indication within the past 90 days were excluded to ensure the reliability of study outcomes.

**Withdrawal Criteria-** Participants who failed to report for a follow-up visit within 15 days of the scheduled date were considered non-compliant and withdrawn from the trial. Additionally, any participant who chose to withdraw consent at any stage of the study was immediately excluded, respecting their autonomy. Cases of loss to follow-up, where participants could not be reached or did not continue with the study procedures, also led to withdrawal. Lastly, if a participant's clinical condition worsened despite the prescribed treatment, posing potential health risks, they were removed from the study to ensure their well-being.

**Study Protocol**
**Intervention**

| **Parameter** | **Details** |
|---|---|
| **Product Used** | Digestive Health Capsules (Ayurvedic proprietary medicine) |
| **Procurement of drug:** | Bombay hemp company |
| **Composition per Capsule** | **Vijayā** (*Cannabis sativa*) – 200 mg<br>**Śuṇṭhī** (*Zingiber officinale*) – 100 mg<br>**Kuṭaja** (*Holarrhena antidysenterica*) – 300 mg<br>**Bilva** (*Aegle marmelos*) – 200 mg |
| **Dosage** | 1 capsule in the morning and 1 capsule at night for 8 weeks. |
| **Study duration** | 8 weeks |

**Assessment criteria**- Quality of life -IBS 36 Scale[12]
**Statistical Analysis-** Data analysis was conducted using appropriate statistical methods to assess the significance of improvements in Quality of life -IBS 36 Scale. Paired t-tests or Wilcoxon signed-rank tests were used to compare pre- and post-intervention scores.

**Table No. 1 Showing the effect of trial medicine on IBS Quality of life – 36 in study group**

| **Symptoms** | **Mean** | | **Diff.** | **% Relief** | **± SD** | **SEM** | **W** | **P** | **Sig.** |
|---|---|---|---|---|---|---|---|---|---|
| Afraid to eat | 4.675 | 1.050 | - 3.625 | 78 | 1.254 | 0.198 | 820.0 | <0.0001 | ES |
| Felt angry | 4.9 | 0.7 | -4.2 | 86 | 1.522 | 0.241 | 780.0 | <0.0001 | ES |
| Need to go suddenly when had a bowel Movement | 4.875 | 0.55 | - 4.325 | 89 | 1.141 | 0.18 | 820.0 | <0.0001 | ES |
| Interfere with relationship with children or partner | 1.825 | 0.25 | - 1.575 | 82 | 1.852 | 0.293 | 190.0 | <0.0001 | ES |
| Avoid food | 4.35 | 1.225 | - 3.125 | 72 | 1.488 | 0.235 | 703.0 | <0.0001 | ES |
| Bowel symptoms interfere with daily activities | 4.275 | 0.475 | -3.8 | 89 | 1.418 | 0.224 | 780.0 | <0.0001 | ES |
| Other thought symptoms were not real | 3.125 | 0.425 | -2.7 | 86 | 1.652 | 0.261 | 528.0 | <0.0001 | ES |
| Discouraged due to bowel problem | 4.450 | 0.425 | -4.05 | 90 | 1.339 | 0.212 | 780.0 | <0.0001 | ES |
| Stop participating in sports activities | 4.325 | 0.675 | - 3.650 | 84 | 1.369 | 0.216 | 780.0 | <0.0001 | ES |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Felt worried about never felling better | 4.625 | 0.575 | -4.05 | 87 | 1.358 | 0.215 | 780.0 | <0.0001 | ES |
| Miss daily activities | 4.25 | 0.3 | - 3.950 | 93 | 1.154 | 0.182 | 780.0 | <0.0001 | E S |
| Bowel symptoms interfere to concentrate | 4.3 | 0.425 | - 3.875 | 90 | 1.114 | 0.176 | 820.0 | <0.0001 | E S |
| Felt isolated from family | 3.4 | 0.4 | -3.0 | 88 | 1.32 | 0.209 | 703.0 | <0.0001 | E S |
| Embarrassed because of bowel symptoms | 4.225 | 0.5 | - 3.725 | 88 | 1.219 | 0.193 | 780.0 | <0.0001 | E S |
| Troubled by abdominal pain | 4.125 | 0.15 | - 3.975 | 96 | 1.847 | 0.292 | 630.0 | <0.0001 | E S |
| Afraid that bowel symptoms were getting worse | 4.8 | 0.425 | - 4.375 | 91 | 1.30 | 0.163 | 820.0 | <0.0001 | E S |
| Troubled by bowel movements that were hard/difficult to pass | 4.525 | 0.4 | - 4.125 | 91 | 1.067 | 0.169 | 820.0 | <0.0001 | E S |

Table shows that trial medicine provided an extremely significant result (P<0.0001) in symptoms like afraid to eat (78%), felt angry (86%), need to go suddenly when had a bowel movement (89%), interfere with relationship with children or partner (82%), avoid food (72%), bowel symptoms interfere with daily activities (89%), other thought symptoms were not real (86%), discouraged due to bowel problem (90%), stop participating in sports activities (84%), felt worried about never felling better (87%), missing daily activities (93%), bowel symptoms interfere to concentrate (90%), felt isolated from family (88%), embarrassed because of bowel symptoms (88%), troubled by abdominal pain (96%), afraid that bowel symptoms were getting worse (91%), troubled by bowel movements that were hard/difficult to pass (91%).

**Table 2: Showing the effect of trial medicine on IBS Quality of life – 36 in study group**

| **Symptoms** | **Mean** | | **Diff.** | **% Relief** | **± SD** | **SEM** | **W** | **P** | **Sig.** |
|---|---|---|---|---|---|---|---|---|---|
| Check diet from the previous day trying to find foods that might cause bowel Symptoms | 4.625 | 0.95 | - 3.67 | 79 | 0.997 | 0.158 | 820.0 | <0.0001 | ES |
| Avoid travelling | 4.275 | 0.625 | -3.65 | 85 | 1.122 | 0.177 | 780.0 | <0.0001 | ES |
| Shorten the length of work time of each day | 4.00 | 0.275 | - 3.72 | 93 | 0.847 | 0.134 | 820.0 | <0.0001 | ES |
| Bowel symptoms disturbed sound sleep | 3.25 | 0.175 | - 3.07 | 94 | 1.047 | 0.166 | 741.0 | <0.0001 | ES |
| Troubled by loose bowel movements | 4.5 | 0.35 | -4.15 | 92 | 1.099 | 0.174 | 820.0 | <0.0001 | ES |
| Symptoms interfere with having sexual relations | 1.825 | 0.425 | -1.4 | 82 | 1.566 | 0.248 | 190.0 | <0.0001 | ES |
| Bloating troubled | 4.7 | 0.275 | - 4.42 | 94 | 0.781 | 0.123 | 820.0 | <0.0001 | ES |
| Symptoms interfere with enjoyment of sport or other activities | 4.075 | 0.225 | -3.85 | 94 | 0.834 | 0.132 | 820.0 | <0.0001 | ES |
| Passing large amount of gas | 5.4 | 0.25 | -5.15 | 95 | 0.662 | 0.105 | 820.0 | <0.0001 | ES |
| Concerned that symptoms may be due to cancer | 2.525 | 0.00 | - 2.52 | 100 | 1.414 | 0.224 | 561.0 | <0.0001 | ES |
| Delay or cancel going out socially | 4.325 | 0.25 | - 4.07 | 94 | 1.095 | 0.173 | 820.0 | <0.0001 | ES |
| Tired in the morning because of bowel symptoms | 4.625 | 0.375 | -4.25 | 92 | 1.149 | 0.182 | 820.0 | <0.0001 | ES |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Bowel symptoms interfere with desire to have sexual relations | 1.875 | 0.175 | -1.7 | 90 | 1.8 | 0.285 | 210.0 | <0.0001 | ES |

Table shows that trial medicine provided an extremely significant result (P<0.0001) in symptoms like check diet from the previous day trying to find foods that might cause bowel symptoms (79%), avoid travelling (85), shorten the length of work time of each day (93%), bowel symptoms disturbed sound sleep (94%), troubled by loose bowel movements (92%), symptoms interfere with having sexual relations (82%), bloating troubled (94%), symptoms interfere with enjoyment of sport or other activities (94%), passing large amount of gas (95%), concerned that symptoms may be due to cancer (100%), delay or cancel going out socially (94%), tired in the morning because of bowel symptoms (92%), bowel symptoms interfere with desire to have sexual relations (90%).

**Table 3: Showing the effect of trial medicine on IBS Quality of life – 36 in study group**

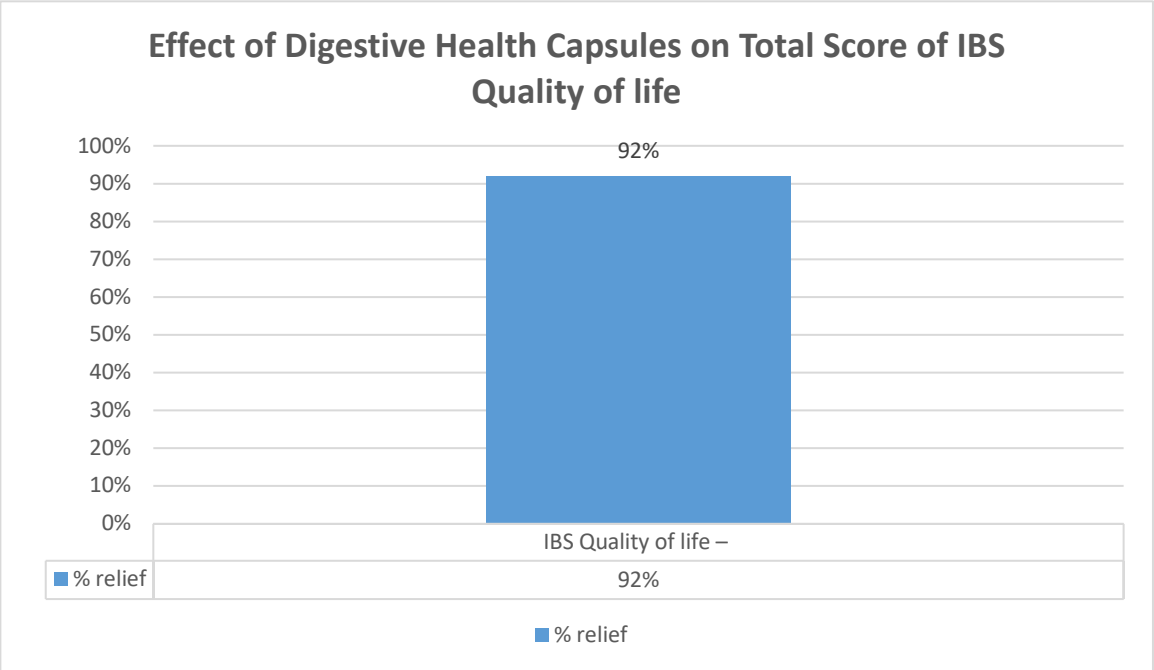
| **Sympto ms** | **Mean** | | **Diff.** | **% Relie f** | **± SD** | **SE M** | **W** | **P** | **Sig.** |
|---|---|---|---|---|---|---|---|---|---|
| | **B. T** | **A. T** | | | | | | | |
| Need to go to the bathroo m even though bowels are empty troubled | 4.275 | 0.225 | -4.05 | 95 | 0.986 | 0.156 | 820.0 | <0.0001 | ES |
| Immedia tely need to find where washroo ms are at new place | 4.075 | 0.35 | -3.75 | 91 | 0.877 | 0.139 | 820.0 | <0.0001 | ES |
| Avoid planning activities ahead of time because unsure of how bowel sympto ms would be | 4.425 | 0.325 | -4.1 | 93 | 1.008 | 0.159 | 820.0 | <0.0001 | ES |
| Accident al soiling of your underwe ar troubled | 2.75 | 0.15 | -2.6 | 95 | 1.336 | 0.211 | 703.0 | <0.0001 | ES |
| Delay work / school /usual daily activities because of bowel symptoms | 4.25 | 0.275 | - 3.975 | 93 | 1.05 | 0.166 | 820.0 | <0.0001 | ES |

Table shows that trial medicine provided an extremely significant result (P<0.0001) in symptoms like need to go to the bathroom even though bowels are empty troubled (95%), immediately need to find where washrooms are at new place (91%), avoid planning activities ahead of time because unsure of how bowel symptoms would be (93%), accidental soiling of your underwear troubled (95%), delay work / school /usual daily activities because of bowel symptoms (93%).

**Table No. 4: Showing the Effect of Digestive Health Capsules on Total Score of IBS Quality of life – 36 in Study Group**

| **IBS- QOL 36 Scale** | **Mean Score** | **% Relief** | **± SD** | **SEM** | **W** | **P** | **Sig.** |
|---|---|---|---|---|---|---|---|
| | 130.15 | 92 | 19.486 | 3.081 | 820 | <0.0001 | ES |

Table shows that trial medicine provided an extremely significant result (P<0.0001) with 92 % of relief on total score of IBS Quality of life -36 Scale.




**Discussion**

Irritable Bowel Syndrome (IBS) is a complex and multifaceted functional gastrointestinal disorder that significantly impacts patients' quality of life. This study aimed to evaluate the effectiveness of Digestive Health Capsules, an Ayurvedic formulation, in managing IBS symptoms and improving overall well-being. The results of the study demonstrated a statistically significant improvement in multiple aspects of IBS-related quality of life, as assessed by the IBS-36 scale.

**Interpretation of Findings**

The findings of this study indicate that Digestive Health Capsules provided significant symptomatic relief across various domains of IBS, including digestive discomfort, bowel movement irregularities, emotional well-being, and social functioning. The study outcomes revealed that participants experienced relief in symptoms such as urgency to defecate, bloating, pain, and avoidance of certain foods, indicating the potential efficacy of this Ayurvedic intervention.

The statistical analysis showed an extremely significant reduction ($P<0.0001$) in several symptoms, including abdominal pain, sudden urgency to defecate, food-related anxiety, and sleep disturbances. Furthermore, emotional symptoms such as anxiety, embarrassment, and worry about worsening bowel health were also significantly alleviated. This suggests that the formulation not only addresses the physiological symptoms of IBS but also provides psychological benefits, aligning with Ayurveda's holistic approach to health.

**Possible Mechanisms of Action**

The therapeutic effects observed in the study can be attributed to the synergistic action of the herbal ingredients present in the Digestive Health Capsules:

1. **Vijayā (Cannabis sativa):** Known for its analgesic, anti-inflammatory, and gut-regulating properties, Vijayā likely contributed to the reduction in abdominal pain and bowel irregularities.[13]
2. **Kuṭaja (Holarrhena antidysenterica):** Traditionally used for managing diarrheal disorders, Kuṭaja may have played a role in stabilizing bowel movements and preventing frequent episodes of diarrhea.[14]
3. **Śuṇṭhī (Zingiber officinale):** Recognized for its carminative and digestive-stimulating effects, Śuṇṭhī may have helped in reducing bloating, improving digestion, and alleviating nausea.[15]
4. **Bilva (Aegle marmelos):** Often used in Ayurvedic treatments for gastrointestinal disturbances, Bilva is known to balance Vāta and Pitta Doṣas, aiding in overall gut health.[16]

**Comparison with Existing Literature**

The results of this study align with existing research on Ayurvedic interventions for IBS. Previous studies have highlighted the efficacy of herbal combinations in regulating gut motility, improving microbial balance, and alleviating stress-related digestive issues. Modern pharmacological research also supports the therapeutic potential of the individual ingredients used in Digestive Health Capsules, reinforcing their role in IBS management.

**Clinical Implications**

The findings of this study suggest that Digestive Health Capsules could serve as a complementary or alternative therapeutic option for IBS management. Given the chronic and relapsing nature of IBS, the long-term use of conventional treatments often leads to dependency and side effects. In contrast, Ayurvedic interventions, with their holistic approach and minimal adverse effects, offer a promising strategy for sustained symptom relief.

Furthermore, the integration of Ayurvedic principles with modern clinical research provides a broader perspective on IBS management, emphasizing the gut-brain connection, dietary modifications, and lifestyle adjustments. The observed improvements in psychological symptoms further highlight the necessity of addressing both physiological and emotional aspects in IBS treatment.

**Conclusion**

The findings of this clinical trial highlight the potential of Ayurvedic intervention in managing Irritable Bowel Syndrome (IBS). The Digestive Health Capsules, formulated with Bilva (Aegle marmelos), Kuṭaja (Holarrhena antidysenterica), Śuṇṭhī (Zingiber officinale), and Vijayā (Cannabis sativa), demonstrated significant improvement in IBS symptoms and overall quality of life. The study revealed substantial reductions in abdominal discomfort, bloating, urgency, psychological distress, and dietary restrictions, as reflected in the IBS-QOL-36 scores. Furthermore, the intervention was well tolerated, with no reported adverse effects, reinforcing its safety and efficacy.

The holistic approach of Ayurveda, which addresses both the physiological and psychological aspects of IBS, appears to be a promising alternative to conventional treatments. The synergistic action of the selected herbal ingredients likely contributed to gut motility regulation, anti-inflammatory effects, and stress modulation, key factors in IBS pathophysiology. The Digestive Health Capsules offer a promising, natural, and holistic treatment approach for IBS, aligning with Ayurvedic principles of gut health restoration. This study paves the way for integrating traditional Ayurvedic formulations into mainstream clinical practice, providing a well-rounded, patient-centered strategy for IBS management.

**Study Limitations and Future Directions**

While the study demonstrated significant improvements in IBS symptoms, certain limitations must be acknowledged:

1. **Lack of a Control Group:** The absence of a placebo or comparative intervention limits the ability to differentiate between the treatment effects and potential placebo responses.
2. **Short Study Duration:** The study duration of 8 weeks, though sufficient for assessing short-term efficacy, may not reflect the long-term benefits or potential recurrence of symptoms.
3. **Small Sample Size:** A larger sample size would enhance the generalizability of the findings and provide a more comprehensive understanding of the formulation's effectiveness across diverse populations.
4. **Dietary and Lifestyle Factors:** While participants were advised to maintain a consistent diet and lifestyle, individual variations in food intake, stress levels, and physical activity may have influenced the outcomes.

Future research should focus on conducting randomized controlled trials (RCTs) with larger sample sizes and extended follow-up periods to validate the findings. Additionally, exploring the gut microbiome changes associated with Ayurvedic treatments could provide deeper insights into their mechanisms of action.

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